IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy	**)**	
Products Liability Litigation Coordinated	**)**	**Case No. 14 C 1748**
Pretrial Proceedings	**)**	**MDL No. 2545**
	)	
(This document applies to all cases)	**)**	

CASE MANAGEMENT ORDER NO. 47
(Ruling on AbbVie's motion for summary judgment on failure-to-warn claims, dkt. 1745)

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation (MDL) proceeding allege that they have suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins (venous thromboembolisms, or VTEs) as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendants AbbVie Inc., Abbott Laboratories, AbbVie Products LLC, and Unimed Pharmaceuticals, LLC (collectively, AbbVie) manufacture AndroGel, one of the TRT drugs at issue in this litigation. Seven plaintiffs have been selected to proceed with bellwether trials beginning June 2017.

Each bellwether plaintiff—Edward Cribbs, Cecile Frost, Jeffrey Konrad, Jesse Mitchell, Arthur Myers, Robert Nolte, and Robert Rowley—alleges that AndroGel caused them to suffer either a cardiovascular or VTE injury. AbbVie has filed three motions for summary judgment, each one addressing different claims or issues. In this opinion, the Court addresses AbbVie's motion for summary judgment on (1) claims based on allegations that AbbVie failed to adequately warn of the dangers of AndroGel; (2) unjust enrichment claims; and (3) punitive damages. For the reasons stated below,

the Court grants AbbVie's motion for summary judgment on plaintiff Rowley's claims for strict liability based on design defect and for breach of implied warranty as well as on all of the plaintiffs' negligent design defect claims but otherwise denies the motion for summary judgment.

Background

The Court assumes familiarity with the background as set out in its separately-issued opinion on AbbVie's motion for summary judgment on the issue of causation. The Court therefore discusses only those details uniquely relevant to plaintiffs' failure to warn claims.

A. Initial approval of AndroGel

In April 1996, AbbVie submitted an investigational new drug application (IND) to the FDA for AndroGel in accordance with the FDA's procedures for approving a new prescription drug. The IND proposed clinical trials to demonstrate the safety and efficacy of AndroGel, a testosterone replacement drug, in treating men with hypogonadism. AbbVie then performed controlled studies of the effects of AndroGel and submitted the data to the FDA. In April 1999, AbbVie submitted a new drug application (NDA) for AndroGel, in which AbbVie was required to demonstrate the drug's efficacy and proposed labeling. In response, the FDA requested that AbbVie provide supplements containing raw data, medical data, and other clinical trial information.

In February 2000, the FDA's medical officer recommended approval of AndroGel 1%. *See* Defs.' Statement of Undisputed Material Facts (SUDMF), Ex. 19 (Application Review for AndroGel 1%). The medical officer concluded that AndroGel 1% was safe

for use and that the clinical trials produced no deaths and no serious adverse events that were determined to be directly related to the use of AndroGel. *Id*. at 5. The medical officer also noted that AndroGel was associated with polycythemia—an elevated volume of red blood cells—in a few clinical trial participants. *Id*. The reviewer indicated, however, that "[c]lear labeling instructions should serve to minimize these risks by recommending active medical surveillance" such as the monitoring of "periodic hematology and chemistry laboratories." *Id*. The medical officer also observed that the mean concentration of estradiol—a metabolite of testosterone and a form of estrogen—of the clinical trial participants remained within normal range on all observation days. *Id*. at 17. The officer also noted that some patients had estradiol concentrations above the upper limit of normal, with a greater number of these patients in the group receiving the higher dose of AndroGel. *Id*.

Later that same month, the FDA approved AndroGel 1% as safe and effective. The approved label indicated that "[h]emoglobin and hematocrit levels should be checked periodically (to detect polycythemia) in patients on long-term androgen therapy." Defs.' SUDMF, Ex. 85 (AndroGel Advertising / Promotional Materials) at E85-0008.

B. Monitoring and developments related to cardiovascular risk

AbbVie says that both it and the FDA continued to monitor available safety information and data for potential risks from AndroGel use, including cardiovascular risk. Specifically, AbbVie monitored safety information to look for evidence of a "safety signal," which the FDA defines as "a concern about an excess of adverse events compared to what would be expected to be associated with a product's use." Defs.'

SUDMF, Ex. 1 (FDA Guidance on Pharmacovigilance Practices) at 4. AbbVie submitted to the FDA annual periodic safety update reports (PSURs), which provided information about adverse events from patient reports, ongoing clinical trials, and medical literature. For the period of February 2000 through February 2005, AbbVie reported thirty-five cardiac events out of 463,200 patient-years of exposure. Defs.' SUDMF, Ex. 33 (2000-05 PSUR) at 2, 14, 16. AbbVie concluded that this incidence of cardiac disorders did not exceed the general frequency in the overall population—and therefore did not constitute a signal—but that it would continue to monitor cardiac risk. *Id*. at 67.

In September 2005, AbbVie provided the FDA with an in-depth analysis of safety information, which it refers to as the 2005 White Paper. *See* Defs.' SUDMF, Ex. 43 (2005 White Paper). AbbVie concluded that no studies reported a link between high endogenous testosterone and increased risk of coronary artery disease. *Id*. at 61. The company determined that any possible unfavorable effects of testosterone on the cardiovascular system are less pronounced at the prescribed doses of AndroGel and thus that the drug is unlikely to alter the overall risk of cardiovascular events. *Id*. at 78. AbbVie concluded that no changes in AndroGel's prescribing information were required "until the potential relationship between TRT and the cardiovascular system is better defined." *Id*. at 104. AbbVie also noted that "[t]here is agreement in the literature that additional research is necessary." *Id*. In both 2007 and 2010, AbbVie conducted additional signal evaluation reports for AndroGel and concluded that there was no evidence of a signal for cardiovascular events. Defs.' SUDMF, Ex 39 (2007 Signal Evaluation) at 7; Defs.' SUDMF, Ex. 40 (2010 Cardiovascular Signal Evaluation) at 12.

In 2010, the FDA received notice that a study evaluating the cardiovascular safety of TRT drugs had been discontinued. *See* Defs.' SUDMF, Ex. 61 (FDA Memo May 2010) at 1. In this study, a group of authors evaluated the use of testosterone gel by elderly men. During testing, the study's data safety and monitoring board recommended that the researchers discontinue the study "because of an increase in cardiovascular events observed among participants treated with testosterone compared to placebo." *Id*. In June of that same year, the authors published the results of this trial and concluded that daily application of a testosterone gel was associated with a greater frequency of adverse events, including cardiovascular events. Defs.' SUDMF, Ex. 60 (Basaria Article) at 115. The authors also noted that due to limitations in the study, the results may have been due to chance alone. *Id*. at 118.

In response to the discontinuation of this study, the FDA undertook a qualitative review of TRT and the risk of cardiovascular disease in adult men. A reviewer for the FDA's division of epidemiology evaluated two meta-analyses and one qualitative review on the topic and determined that the studies highlight some trends "that could represent signals of unknown effects of TRT" and that such trends "include a possible increased risk of cardiovascular events . . . in men aged 65 years or older." FDA Memo May 2010 at 1. The FDA nevertheless concluded that the results of these studies "do not support an association between TRT and increased risk of cardiovascular events in men." *Id*. The FDA also noted that the analyses fell short of providing a definitive answer and that larger safety trials designed to evaluate cardiovascular outcomes were needed to provide a more conclusive answer. *Id*. The FDA also evaluated the Basaria article and determined that it had several limitations "that precluded a definitive assessment of the

role of testosterone therapy in the cardiovascular events noted in the study." Defs.' SUDMF, Ex. 4 (Resp. to Citizen Petition) at 6.

Later in 2010, the FDA conducted another analysis of cardiovascular risk. This time, the FDA evaluated all of the studies discussed within the three articles that the FDA reviewed in May. Defs.' SUDMF, Ex. 63 (FDA Memo Dec. 2010) at 1. The FDA concluded that "one cannot make the conclusion based on these studies that testosterone therapy increases the risk of cardiovascular disease." *Id*. The memo also identified the need for long-term studies focused on evaluating cardiovascular risk. *Id*. The FDA noted that the label then in use for testosterone products (including AndroGel) included a warning on risk of edema in patients with preexisting cardiac, renal, or hepatic disease. *Id*. at 2. It went on to state that "the risk of myocardial infarction and other cardiovascular disease remains uncertain." *Id*.

Following these evaluations, the FDA finally ruled on a new drug application that AbbVie had first submitted in February 2009 for a new version of AndroGel: AndroGel 1.62%. In reviewing the new drug application for AndroGel 1.62%, the FDA considered adverse event reports for AndroGel 1% and specifically the possibility of an increased risk of cardiovascular injury. Defs.' SUDMF, Ex. 68 (Application Review for AndroGel 1.62%) at 107. The FDA pointed to its own December 2010 determination that available scientific studies "do not support an association between TRT and an increased risk of cardiovascular events in men." *Id*. at 108. The FDA did not require the label for AndroGel 1.62% to include a warning regarding an increased risk of cardiovascular events.

Between April 2013 and February 2014, three additional articles were published

that are relevant to this litigation. The first was a meta-analysis known as the Xu article which evaluated the existing literature on whether there is an association between use of testosterone and cardiovascular risk. The other two publications—the Vigen article and the Finkle article—were independent studies that evaluated the same association.

In February 2014, the group Public Citizen submitted a citizen petition to the FDA asking it to issue a warning that TRT increases risk of cardiovascular injury. *See generally* Defs.' SUDMF, Ex. 74 (Citizen Petition). In doing so, Public Citizen relied on the articles by Basaria, Xu, Vigen, and Finkle to argue that a causal association existed between TRT and cardiovascular injury. The citizen petition asked the FDA to (1) add a "black box" warning to the labels for all drugs containing testosterone highlighting the increased risks of cardiovascular dangers; (2) send "Dear Doctor" letters to warn physicians of the possibility of cardiovascular effects; and (3) require the medication guide for all testosterone products to be updated to reflect this risk. *Id*. at 1.

The FDA denied the citizen petition's requests in July 2014. It concluded that there was "insufficient evidence of a causal link between testosterone therapy and adverse cardiovascular outcomes to support the [requested] regulatory actions." Resp. to Citizen Petition at 5. The FDA again addressed the Basaria study and stated that its limitations prevented a conclusion that testosterone caused the cardiovascular effects. *Id*. at 6. The FDA evaluated the Xu, Vigen, and Finkle articles and concluded that they similarly did not support the conclusion that TRT drugs increase the risk of cardiovascular events. *Id*. at 7–14. The agency denied the requested labeling changes but indicated that the studies warranted "further exploration of a possible safety signal regarding testosterone and cardiovascular risk." *Id*. at 16. The FDA stated that its

evaluation of the possible safety signal was ongoing. Specifically, it was waiting for the results from a trial investigating the effects of testosterone in men over sixty-five, and it planned to present the question of a potential association between testosterone and cardiovascular risk to an advisory committee in the fall. *Id*.

In September 2014, the FDA convened an advisory committee to consider "the potential for adverse cardiovascular outcomes" associated with use of TRT. Defs.' SUDMF, Ex. 75 (Minutes Summary of September 2014 Advisory Committee Meeting) at 2. The advisory committee agreed that available studies about cardiovascular risk were limited in scope and quality but also agreed that a weak signal of cardiovascular risk had emerged from the results of recent large epidemiologic studies. *Id*. at 7. The committee decided that the potential signal for cardiovascular risk should be added to the labeling for TRT drugs. *Id*.

In May 2015, the FDA required AbbVie to add the following warning to the AndroGel label:

> **5.5 Cardiovascular Risk**
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> Long term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. To date, epidemiologic studies and randomized controlled trials have been inconclusive for determining the risk of major adverse cardiovascular events (MACE), such as non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death, with the use of testosterone compared to non-use. Some studies, but not all, have reported an increased risk of MACE in association with the use of testosterone replacement therapy in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use AndroGel 1.62%.

Defs.' SUDMF, Ex. 77 (May 2015 AndroGel 1.62% Label) at 5.5.

C. Monitoring and developments related to VTE risk

AbbVie also monitored the relationship between TRT and VTE events and

provided the FDA with PSURs that included reports on adverse clotting events. Between 2002 and 2004, the PSURs reported two serious cases of pulmonary embolism and one major case of deep vein thrombosis (DVT). A PSUR that evaluated safety data from 2000 through 2005 reported four serious thromboembolic events (both DVT and pulmonary embolism) that were deemed to be possibly related to AndroGel. In August 2005, AbbVie revised the "Adverse Reactions" section of the AndroGel label to note that "[t]wo patients reported serious events considered possibly related to treatment: deep vein thrombosis (DVT) and prostate disorder requiring a transurethral resection of the prostate (TURP)." Defs.' SUDMF, Ex. 45 (Aug. 2005 AndroGel 1% Label) at 11.

In AbbVie's 2005 White Paper, the company addressed AndroGel's hematologic effects in addition to the cardiovascular risks. *See* 2005 White Paper 45–52. The report acknowledged that testosterone can stimulate red blood cell production, which can lead to polycythemia. *Id*. at 45. For this reason, AbbVie recommended that the label continue to recommend monitoring of hemoglobin and hematocrit. *Id*. AbbVie also noted that elevated hematocrit can lead to thromboembolic events. *Id*. at 47. The report evaluated adverse event reports from the company's database from February 2000 through February 2005 and found 45 instances of polycythemia and increased hematocrit out of 463,200 patient-years of observation. *Id*. at 50. AbbVie also found four thromboembolic events—two cases of DVT and two cases of pulmonary embolism—all of which were considered serious. *Id*. Elevated hematocrit was observed in only one of these cases. *Id*. AbbVie concluded that "[t]he underlying medical conditions of the four patients" were the most plausible explanations for the

VTE events. *Id*. The company stated that it is unlikely that the events were caused by testosterone gel. *Id*.

The report also analyzed adverse event reports from the FDA database on multiple testosterone drugs, including AndroGel. *Id*. at 50–51. AbbVie discovered eighty-two cases of hematologic adverse events, including polycythemia, increased hematocrit, and thrombosis-related events. *Id*. at 51. Twenty of these cases identified a testosterone product as the primary or secondary suspect medication; eight specifically identified AndroGel. *Id*. Of the eight associated with AndroGel, there were two instances of DVT, one instance of increased hematocrit, and three instances of pulmonary embolism. *Id*.

In March 2007, AbbVie again considered the possibility of a connection between TRT and VTE events. *See* Defs.' SUDMF, Ex. 39 (2007 VTE Signal Evaluation). AbbVie noted two reports of venous thrombus activity between February 2007 and February 2008. *Id*. at 1–2. The company ultimately concluded that a review of scientific literature did not support a signal of VTE risk associated with the use of TRT drugs. *Id*. at 7.

In December 2007, the FDA approved a new label for AndroGel. The company updated the label to indicate: "Increases in hematocrit, reflective of increases in blood cell mass, may require lowering or discontinuation of testosterone. Increase in blood cell mass may increase the risk for a thromboembolic event." Defs.' SUDMF, Ex. 83 (Dec. 2007 AndroGel 1% Label) at 5.9. In September 2009, the FDA again approved a new label. This time, AbbVie added a statement to the medication guide for patients which listed as a possible side effect "[b]lood clots in the legs." Defs.' SUDMF, Ex. 47

(Medication Guide) at ABBVIE-FST17796240.

In March 2010, AbbVie received an adverse event report of DVT with pulmonary embolism and subsequently conducted a signal evaluation. *See* Defs.' SUDMF, Ex. 84 Part 3 (2010–11 PSUR) at E84-0866. AbbVie concluded "that the potential signal of VTE was not supported by the data available to date." *Id*. at E84-0880. The evaluation further stated that the then-current warning—which advised patients to monitor hematocrit for polycythemia—adequately reflected available scientific knowledge. *Id*.

As previously discussed, in April 2011 the FDA approved AndroGel 1.62%. The FDA's medical review of the product noted that in clinical studies recipients of AndroGel 1.62% did demonstrate an overall increase in mean hematocrit. Application Review for AndroGel 1.62% at 157. There were no thromboembolic events reported in these patients. *Id*. The FDA concluded that the language in the proposed label, which mirrored that of AndroGel 1%, adequately addressed the possibility of increased hematocrit. *Id*. But the FDA also moved the discussion of possible increased hematocrit from the "Laboratory Testing" section under warnings into a separate section under warnings titled "Polycythemia." *Compare* Dec. 2007 AndroGel Label at 5.9 and Defs.' SUDMF, Ex. 86 (April 2011 AndroGel 1.62% Label) at 5.3. Section 5.3 of the April 2011 label states:

> **5.3 Polycythemia**
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> Increases in hematocrit, reflective of increases in red blood cell mass, may require lowering or discontinuation of testosterone. Check hematocrit prior to initiating treatment. It would also be appropriate to re-evaluate the hematocrit 3 to 6 months after starting treatment, and then annually. If hematocrit becomes elevated, stop therapy until hematocrit decreases to an acceptable concentration. An increase in red blood cell mass may increase the risk of thromboembolic events.

April 2011 AndroGel 1.62% Label at 5.3.

In March 2014, the FDA notified AbbVie that it had "become aware of new safety information related to the serious risk of venous thromboembolic events associated with testosterone use." Defs.' SUDMF, Ex. 87 (2014 Safety Labeling Change Notification) at ABBVIE-FST06145227. The FDA requested that AbbVie add additional safety information to the AndroGel labeling. *Id*. Specifically, the FDA asked AbbVie to add to the warnings and precautions section under the highlights heading the following statement: "Testosterone use may increase the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE). Consider VTE in patients with signs or symptoms consistent with DVT or PE." *Id*. The FDA also required AbbVie to add to the full prescribing information the following warning and precaution:

> **5.4 Venous Thromboembolism**
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> There have been postmarketing reports of venous thromboembolism (VTE) in men taking testosterone, including AndroGel 1%. Testosterone use may increase the risk of VTE, including deep vein thrombosis (DVT) and acute pulmonary embolism (PE). Consider VTE in patients who report symptoms of pain, swelling, warmth and redness in the leg (DVT) or acute shortness of breath (PE). In such patients, discontinue treatment with AndroGel 1% and evaluate patients for possible VTE *[see Postmarketing Experience (6.2)]*.

Id. at ABBVIE-FST06145228. Finally, the FDA required AbbVie to update the warning in the medication guide regarding blood clots in the legs to read: "**Blood clots in the legs or lungs.** Clots in your leg can include leg pain, swelling or redness. Clots in your lungs can include difficulty breathing or chest pain." *Id*.

In response, AbbVie analyzed available VTE safety data from February 2000 through March 2014 and submitted to the FDA another white paper summarizing its findings. *See* Defs.' SUDMF, Ex 89 (2014 White Paper). The report noted that

although polycythemia may lead to an increased incidence of vascular events, "randomized testosterone trials have reported very low frequency of thromboembolic events with testosterone therapy." *Id*. at 17. The report also addressed the possibility that TRT leads to VTE events not through polycythemia but through an increase in estradiol. *See id*. The report indicated that "the modest increases in estradiol that accompanies [sic] most forms of TRT (e.g., transdermal) are unlikely to account for any increased propensity for thrombotic events." *Id*.

The FDA evaluated this "rebuttal response" and modified its label change requirements "to better reflect the level of uncertainty of drug causality." Defs.' SUDMF, Ex. 90 (2010 E-mail) at 2. Specifically, the FDA told AbbVie it was not required to add to the warnings and precautions section the statement indicating that testosterone use may increase the risk of VTE and that patients with certain symptoms should be evaluated for VTE. *Id*. at 3. The FDA also removed from its requirement for the full prescribing information the statements indicating that testosterone use may increase the risk of VTE, including DVT and pulmonary embolism. *Id*. AbbVie added the modified warnings required by the FDA to the AndroGel label in June 2014.

D. The present suits

The seven bellwether plaintiffs addressed in this motion have each filed suit against AbbVie, alleging that they suffered either a cardiovascular or VTE injury after taking AndroGel. This opinion addresses only the plaintiffs' claims based on AbbVie's alleged failure to warn. All of the bellwether plaintiffs allege that AbbVie is liable for both negligence and negligent misrepresentation based on its failure to warn consumers of AndroGel about the increased risk of cardiovascular and VTE injury. Five of the

plaintiffs—Frost, Konrad, Mitchell, Nolte, and Rowley—also allege that AbbVie is strictly liable for its failure to warn and for manufacturing AndroGel with a defective design. All of the bellwether plaintiffs allege that AbbVie has breached an implied warranty by failing to disclose defects in AndroGel. Six of the plaintiffs—Frost, Konrad, Mitchell, Myers, Nolte, and Rowley—allege that AbbVie has also breached express warranties and engaged in fraud. Myers and Rowley allege that AbbVie's failure to warn constitutes a violation of state consumer protection laws. And Mitchell and Nolte allege that AbbVie is *per se* negligent because it violated the Food, Drug, and Cosmetic Act by failing to provide adequate warnings. In addition, all seven bellwether plaintiffs seek punitive damages based on these failure to warn claims. Cribbs also brings a claim for unjust enrichment and seeks to collect from AbbVie the money he paid for AndroGel.

Discussion

AbbVie has moved for summary judgment on the bellwether plaintiffs' claims based on failure to warn, as well as their request for punitive damages and Cribbs's unjust enrichment claim. AbbVie argues first that the failure to warn claims are preempted by federal law. Alternatively, AbbVie contends that the plaintiffs' failure to warn claims fail under state law because (1) there is no evidence that AbbVie knew or should have known that AndroGel increased risk of cardiovascular or VTE injury; and (2) the warnings that AbbVie provided were adequate to warn of the known or knowable risks associated with AndroGel. AbbVie further contends that four of the plaintiffs—Cribbs, Konrad, Myers, and Rowley—have not provided evidence that AbbVie's alleged failure to provide adequate warnings was the proximate cause of their injuries. AbbVie also argues that Myers's failure to warn claims are barred by the statute of limitations.

In addition, AbbVie argues that it is entitled to immunity from the plaintiffs' strict liability claims based on design defect and their claims based on breach of an implied warranty. AbbVie also argues that the plaintiffs' claims based on negligent design defect are preempted by federal law. Finally, AbbVie contends that the plaintiffs are not entitled to punitive damages and that Cribbs's claim for unjust enrichment fails because he did not directly bestow a benefit on AbbVie.

When considering a motion for summary judgment, a court construes the facts in the light most favorable to the non-moving party. *Suarez v. W.M. Barr & Co., Inc.*, 842 F.3d 513, 517 (7th Cir. 2016). Summary judgment is appropriate where there is no genuine dispute regarding any material fact and the moving party is entitled to judgment as a matter of law. *Schaefer v. Universal Scaffolding & Equip., LLC*, 839 F.3d 559, 604 (7th Cir. 2016). A dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Whiting v. Wexford Health Sources, Inc.*, 839 F.3d 658, 661 (7th Cir. 2016).

A. Preemption

AbbVie first argues that the plaintiffs' claims based on the company's alleged failure to warn are preempted by federal law. Federal preemption occurs when a state law is invalidated because it conflicts with federal law. *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 390 (7th Cir. 2010). Courts have identified three forms of preemption: (1) express preemption, where Congress declares its intent to preempt state law; (2) implied preemption, where the structure and purpose of the federal law evinces an intent by Congress to preempt state law; and (3) conflict preemption, which occurs when it is impossible to comply with both federal and state law. *Id*. AbbVie

argues that the failure to warn claims fall into the third category, because it is impossible to comply with both federal labeling requirements from the FDA and state-law duties that underlie failure to warn claims. *See* Defs.' Mot. for Summ. J. on Pls.' Failure-To-Warn Claims and Mem. of Law in Support (Defs.' Mot. for Summ. J.) at 55.

The Supreme Court has held that conflict preemption exists for state-law claims based on a manufacturer's alleged failure to warn consumers only when there is clear evidence that the FDA would have rejected the proposed change to the drug's label. *Wyeth v. Levine*, 555 U.S. 555, 571–72 (2009); *Mason*, 596 F.3d at 391. In doing so, the Court relied on the FDA's procedures regarding labeling changes. The Court noted that typically a manufacturer may only change a drug label after receiving approval from the FDA. *Wyeth*, 555 U.S. at 568. FDA regulations qualify this restriction, however, and indicate that a manufacturer may "add or strengthen a contraindication, warning, precaution, or adverse reaction" without waiting for FDA approval. *Id.* (citing 21 CFR §§ 314.70(c)(6)(iii)(A), (C)). Thus manufacturers are not limited to the warnings approved by the FDA but may unilaterally add additional warnings—and thereby comply with state-law duties under failure to warn—without violating federal requirements. *Wyeth*, 555 U.S. at 569–71. Conflict preemption therefore exists in this context only where the manufacturer can provide "clear evidence" that the FDA would have rejected attempts by the manufacturer to make the change to the label that plaintiffs contend was omitted. *Id*. at 571–72; *Mason*, 596 F.3d at 391. The Court concludes that AbbVie has failed to present clear evidence that the FDA would have rejected efforts to add warnings about either cardiovascular or VTE risk to the AndroGel warning labels.

AbbVie first argues that the FDA considered any potential risks when it initially

approved AndroGel in 2000, because it concluded that the drug was safe and did not require a warning about either cardiovascular or VTE risk. Defs.' Mot. for Summ. J. at 59. But the Seventh Circuit stated in *Mason* that the FDA's initial approval of a drug "does not provide much, if any, evidence that the FDA would have rejected the warning the plaintiffs say should have been in place." *Mason*, 596 F.3d at 391. The court emphasized the fact that the manufacturer, and not the FDA, retains primary responsibility for a drug's label. *Id*. In short, the fact that the FDA accepted AbbVie's assessment of the risks of AndroGel and approved the label that AbbVie proposed sheds little light on whether the FDA would have rejected any attempts by AbbVie to provide additional warnings.

AbbVie next argues that the FDA had been evaluating and approving TRT drugs since the early 1970s and never required the warnings that plaintiffs now allege were missing. Defs.' Mot. for Summ. J. at 60. AbbVie contends that the FDA repeatedly determined that TRT products did not present the types of risk that plaintiffs now claim. But again, the Seventh Circuit in *Mason* determined that the administrative history of "different drugs made by different manufacturers" is not useful in determining whether the clear evidence standard has been met. *Mason*, 596 F.3d at 395. To put it another way, the FDA's failure to require warnings on the labels of different drugs does not answer whether they would have rejected an attempt by AbbVie to add the warning to its own labels.

AbbVie also points to the fact that over the years it provided the FDA with multiple analyses of potential safety signals and adverse event reports, including annual PSURs and comprehensive white papers. Defs.' Mot. for Summ. J. at 61. AbbVie

contends that in each of these instances, it analyzed the possibility of cardiovascular or VTE risk, and yet the FDA never required additional warnings in response to these analyses. Further, AbbVie notes, the FDA approved numerous AndroGel labels between 2000 and 2009 without requiring the labeling changes that plaintiffs now endorse. This, AbbVie argues, constitutes clear evidence that the FDA would have rejected any attempt by AbbVie to add such warnings themselves. *Id*. But in each of the reports in question, AbbVie concluded that there was no evidence of an association between AndroGel and either cardiovascular or VTE risk, and it consistently recommended that no change be made to AndroGel's labeling. The fact that the FDA accepted AbbVie's recommendation to maintain the current warnings does not constitute clear evidence that it would have rejected an additional warning. Nor does the fact that the FDA repeatedly approved labels that did not contain the warning. *See Mason*, 596 F.3d at 395 (finding that "the FDA's inaction, as in its failure to mandate a warning about the risk," does not support granting summary judgment on preemption). The Court concludes that the plaintiffs' failure to warn claims are not preempted.

AbbVie next points to the fact that the FDA evaluated the possibility of an association between TRT drugs and either cardiovascular or VTE risk and consistently concluded that there was insufficient evidence to draw a causal connection. AbbVie points to the following determinations by the FDA:

- the FDA's conclusion in 2010 that the risk of cardiovascular disease "remains uncertain" following the publication of the Basaria article, FDA Memo Dec. 2010 at 2;
- the FDA's conclusion in 2013 based on a safety review of AndroGel 1.62% that "known safety issues associated with [AndroGel] are adequately addressed in the current labeling," Defs.' SUDMF, Ex. 70 (2013 AndroGel 1.62% Postmarketing Safety Summary) at 4.

- the FDA's conclusion in 2014 following further study that there was insufficient evidence of a causal link between testosterone therapy and cardiovascular injuries, Resp. to Citizen Petition at 5.

But the fact that the FDA was not "affirmatively convinced of a causal link between the drug and the adverse event" would not necessarily preclude AbbVie from adding the warning on its own. *See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 298 (3d Cir. 2017). As in *Fosamax*, the FDA recognized the possibility of a link with both cardiovascular and VTE risk, even though it ultimately concluded that the available literature did not support an association. *See* FDA Memo May 2010 at 1; Minutes Summary of September 2014 Advisory Committee Meeting at 7. And as AbbVie points out, the FDA approved three labeling changes between August 2005 and September 2009 that added additional information relating to the possibility of VTE injury, though not going so far as to state a causal relationship. *See* Defs.' Mot. for Summ. J. at 62–63. This evidence indicates a reasonable possibility "that the FDA would still have determined that 'reasonable evidence' of a link existed—or more precisely, that the possibility of rejection was less than highly probable." *Fosamax*, 852 F.3d at 298. AbbVie has therefore failed to meet the "clear evidence" standard.

Finally, AbbVie points to two instances in which, it argues, the FDA rejected the specific warnings that plaintiffs now argue were missing. In March 2014, the FDA asked AbbVie to add the following statement to AndroGel's full prescribing information: "Testosterone use may increase the risk of VTE, including deep vein thrombosis (DVT) and acute pulmonary embolism (PE)." 2014 Safety Labeling Change Notification at 1–2. AbbVie then conducted its own review of VTE safety information and concluded that it was unlikely that TRT drugs led to increased risk of VTE, through either polycythemia or other mechanisms. *See* 2014 White Paper. The FDA responded by deleting its

earlier statement from its warning requirement. 2010 Email at 2–3. AbbVie argues that this amounts to a clear rejection by the FDA of the warning language that plaintiffs rely on for their claims. But as AbbVie points out, this was a rejection of the FDA's *own* proposal, and not a rejection of an attempt by AbbVie to add the language. This evidence does not demonstrate that, had AbbVie amended the label to include the language in the FDA's initial proposal instead of contesting the language, the FDA would have rejected this modification.

The other instance that AbbVie points to is the FDA's rejection of the 2014 citizen petition. The citizen petition asked the FDA to require a black box warning, Dear Doctor letters, and an update to the medication guide to warn consumers of cardiovascular risk associated with testosterone products. Citizen Petition at 1–2. The FDA ultimately denied all three requests and indicated that the current evidence presented at most a "possible safety signal." Resp. to Citizen Petition at 16. AbbVie relies on two circuit court cases in arguing that this meets the clear evidence standard. In the first, the Seventh Circuit indicated that the FDA's refusal to require a reference to a particular injury on the label of an over-the-counter drug "when it had been asked to do so in the submission to which the agency was responding" was clear evidence that the FDA would not approve a similar warning from the manufacturer. *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010). The Tenth Circuit reached a similar conclusion last week in *Cerveny v. Aventis, Inc.*, No. 16-4050, 2017 WL 1573309 (10th Cir. May 2, 2017), finding the FDA's rejection of "a citizen petition containing arguments virtually identical" to plaintiffs' to be clear evidence supporting preemption. *Id*. at *9.

First, the Court notes that the Seventh Circuit in *Robinson* was not addressing an argument regarding preemption. Rather, it was evaluating the plaintiff's claim that the district court erred in refusing to permit her to amend her complaint to add a claim based on breach of implied warranty. Because the issue of preemption was not raised by either party, the court's statement regarding what constitutes clear evidence is dicta.

More importantly, the facts of this case distinguish it from both *Robinson* and *Cerveny* and therefore support the conclusion that AbbVie has failed to meet the standard for preemption. In *Robinson*, the FDA declined to include the proposed warning after it determined that "the addition would confuse rather than enlighten." *Id*. at 870. The FDA specifically stated that "the overall benefit versus risk profile for ibuprofen products remains very favorable when they are used according to the labeling instructions." *Id*. But in AbbVie's case, the FDA did not indicate that the warning requested in the citizen petition would confuse or otherwise discourage consumers for whom the drug was beneficial from taking TRT drugs. In fact, the FDA agreed that the evidence might demonstrate a "possible safety signal." Resp. to Citizen Petition at 16.

The FDA's rejection of a citizen petition in *Cerveny* is somewhat closer to the rejection upon which AbbVie relies here. In considering the citizen petition at issue in that case, the FDA stated that "the scientific literature did not justify ordering changes to the labeling that warn of such risks" and "there was insufficient evidence to support [the other] requests." *Cerveny*, 2017 WL 1573309, at *7. The Tenth Circuit found that the FDA, in its rejection of the petition, "concluded that the warnings were unjustified for risks in taking [the drug] prior to pregnancy" and therefore that the claims were preempted. *Id*. at *10. In the present case, the FDA also concluded that there was

insufficient evidence to support the warnings requested by the citizen petition. But, the FDA also indicated uncertainty, and a less-than-definitive determination, by stating that it "believes that the publication of these studies warrants further exploration of a possible safety signal regarding testosterone and cardiovascular risk" and that the FDA's "evaluation remains ongoing." Resp. to Citizen Petition at 16. The FDA noted that it was continuing to assess "this potential safety signal" and was waiting for the results of a trial evaluating the effects of testosterone treatment in elderly men. *Id*. Finally, the FDA stated that it intended to present the question of a potential association between testosterone and cardiovascular events to an advisory committee. *Id*. This evidence indicates that there may have been other reasons behind the FDA's denial of the citizen petition—namely, that it wanted to complete its own evaluation—that caused it to reject the citizen petition and that it would not have rejected a similar proposal from the manufacturer itself. *See Mason*, 596 F.3d 387, 394–95 (finding that rejection of a citizen petition did not constitute clear evidence where the FDA indicated that more research was necessary). Although the court in *Cerveny* rejected plaintiffs' argument that the FDA would have treated a request by the manufacturer differently than one in a citizen petition, *Cerveny*, 2017 WL 1573309 at *8–9, the FDA's statements in this case indicate that, had the manufacturer come forward with a request to make further warnings, the FDA may have permitted the changes. And irrespective of the rationale for the FDA's determination, its rejection of the warnings is not "clear-cut," *Mason*, 596 F.3d at 394, because the agency itself indicated the possibility of future action.[1]

[1] The Court also notes that in May 2015, the FDA required AbbVie to add additional warnings about cardiovascular risk to the AndroGel label, based on part on the findings of the advisory committee referenced in the agency's response to the citizen petition.

Further, the citizen petition in this case requested that the labeling changes apply to "all testosterone-containing drugs presently on the market," not only to AndroGel. Citizen Petition at 1. This change would therefore have swept much more broadly than an attempt by AbbVie to change only the AndroGel label. This is significantly different from *Cerveny*, where, as far as the Court can tell, the citizen petition requested changes specifically to the label of the drug taken by one of the plaintiffs. *See Cerveny*, 2017 WL 1573309 at *7. *Cerveny* itself provides the importance of this distinction: "the FDA views overwarnings as problematic because they can render the warnings useless and discourage use of beneficial medications." *Id*. at *8. This rationale may explain not only why the FDA may be reluctant to add too many warnings to the label of a particular product, but also why the agency may be reluctant to add a particular warning to the label of a number of products that may be varied in design and use. Thus the FDA's rejection in *Cerveny* of the citizen petition's proposed warning for the precise drug at issue—i.e., a warning that was narrow and focused—constituted clear evidence that it would have rejected a similar attempt by the manufacturer. But the FDA's rejection in this case of the citizen petition's effort to modify the labels of "all testosterone-containing drugs" does not constitute clear evidence that the agency would have rejected an attempt by AbbVie to modify the warning label of only its own drug.

In sum, because there are other explanations for the FDA's rejection of the citizen petition, this rejection does not constitute clear evidence that the FDA would have rejected an attempt by AbbVie to add the warnings that plaintiffs contend were

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Though the significance of this point may be subject to question, *see Mason*, 596 F.3d at 395, "[t]o the extent these subsequent events have any sway . . . they clearly cut towards making it less likely that the FDA would have rejected plaintiffs' proposed warning." *Id.* at 395.

wrongfully omitted.

Finally, AbbVie argues that plaintiffs cannot defeat preemption by arguing that the company committed fraud on the FDA. Defs.' Mot. for Summ. J. at 80. Plaintiffs concede that their failure to warn claims do not rely on allegations that AbbVie committed fraud on the FDA or withheld information from the agency. Pls.' Resp. in Opp'n to Mot. of AbbVie Defs.' for Summ. J. on Pls.' Failure To Warn Claims (Pls.' Resp.) at 23. Therefore this argument is moot.

For all of these reasons, the Court finds that AbbVie has failed to present clear evidence that the FDA would have rejected an effort by AbbVie to add the requested labeling changes to the AndroGel label. The Court therefore concludes that plaintiffs' failure to warn claims are not preempted.

B. Failure to warn

Failure to warn claims are a product of state law, and the seven bellwether plaintiffs reside in six different states. The law underlying failure to warn claims, however, is largely similar across these states. The Court will make note of any significant differences that impact its analysis.

Under a failure to warn claim, a product may be deemed defective if it is unreasonably dangerous to place the product in the hands of a user without a suitable warning and the product is supplied and no warning is given. *See, e.g.*, *Saller v. Crown Cork & Seal Co., Inc.*, 115 Cal. Rptr. 3d 151, 166, 187 Cal. App. 4th 1220, 1238 (2010). Plaintiffs must show that the defendant "did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge," which is typically measured by the information available at the

time of the manufacture and distribution. *Id*., 187 Cal. App. 4th at 1238; *see also McKenzie v. A.W. Chesterson Co.*, 277 Or. App. 728, 742, 373 P.3d 150, 158 (2016); *Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 541 (Tenn. 2008); *House v. Armour of Am., Inc.*, 929 P.2d 340, 343 (Utah 1996). In the prescription drug context, manufacturers have a continuing duty to warn about the risks associated with their products, even those discovered past the point of initial sale. *See Payne v. Novartis Pharm. Corp.*, 767 F.3d 526, 530 (6th Cir. 2014); *Singleton v. Eli Lilly, Co.*, No. 1:10-CV-02019-AWI-SKO, 2011 WL 2621067, at *3 (E.D. Cal. June 29, 2011). This duty to warn also requires the manufacturer to "exercise ordinary and reasonable care in testing a product for potential danger." *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012). Thus a manufacturer's failure to investigate risks of potential harm can create liability under failure to warn, but not for "hidden risks that neither it nor the medical community had a reasonable basis to suspect." *Id*.

Further, all of the states whose law is at issue in the AbbVie bellwether trial cases apply the learned intermediary doctrine, under which the manufacturer's duty to warn extends only to prescribing physicians and not to consumers of the drug itself. *See Walton v. Bayer Corp.*, 643 F.3d 944, 999–1000 (7th Cir. 2011) (applying Illinois law). The physician is a "learned intermediary" "who, equipped with the knowledge imparted to him by the drug's manufacturer, determines, weighing benefit against risk, the drug's suitability for a particular patient." *Id*. at 1000. Because the physician determines whether to prescribe the drug, manufacturers are required to provide only warnings sufficient to make the physicians aware of the attendant risks of a particular medication.

Finally, plaintiffs bringing failure to warn claims must also demonstrate that the manufacturer's failure to provide adequate warnings was the proximate cause of their injuries.

In moving for summary judgment, AbbVie argues that (1) it did not know, nor should it reasonably have known, that AndroGel caused increased risk of cardiovascular or VTE injury prior to the plaintiffs' injuries; (2) the warnings on the AndroGel label were adequate to warn physicians of the known risks; and (3) four of the plaintiffs have not provided evidence to support proximate causation.

1. Knew or should have known

A drug manufacturer is deemed to be an expert in its field and is under a continuing duty to be aware of scientific developments relating to its product. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 98 (Utah 1991). Manufacturers are therefore responsible not only for "actual knowledge gained from research and adverse reaction reports, but also for constructive knowledge as measured by scientific literature and other available means of communication." *Id*. Manufacturers are required to notify the medical profession of any additional side effects discovered from the use of their products. *Id*.

Because a prescription drug manufacturer has an ongoing duty to inform the medical profession about the risks associated with its product even after the time of distribution, the Court must consider all information available to AbbVie at any time prior to the plaintiffs' injuries, the idea being that had AbbVie issued a warning even after the plaintiffs had initially been prescribed AndroGel, they might have ceased taking the drug and thereby avoided their injuries. At times, the relevant scientific literature differs for

cardiovascular and VTE risks, and therefore the Court considers them separately.

a. Information on cardiovascular risk

Four bellwether plaintiffs allegedly suffered a cardiovascular injury after taking AndroGel:

- Cribbs (myocardial infarction on May 25, 2012)
- Frost (myocardial infarction on February 21, 2013)
- Konrad (myocardial infarction on July 9, 2010)
- Mitchell (myocardial infarction on November 18, 2012)

The Court considers the scientific literature and other medical information available to AbbVie prior to these dates. Neither party argues that there was any scientific information made available between the first cardiovascular injury (July 2010) and the last (February 2013) that might differentiate the Court's determination as between these four plaintiffs. *See* Defs.' Mot. for Summ J. at 88–90.

The Court concludes that a reasonable jury could find that AbbVie knew or reasonably should have known, before the injuries suffered by these four plaintiffs, that TRT drugs increase the risk of cardiovascular injury. In support of their argument, plaintiffs first offer two reports by experts who describe the mechanisms by which testosterone can lead to cardiovascular injuries. In the first report, Dr. Perry Halushka discusses a particular mechanism involving thromboxane A2 receptors. He explains how thromboxane A2 plays a central role in platelet aggregation, and he opines that a "robust body of medical and scientific literature" demonstrates that platelet factors play a critical role in acute thrombotic events. Pls.' Resp. to Defs.' Statement of Material Facts (SOMF), Ex. 2 (Halushka Report) at 8. In the second report, Dr. Burt Gerstman discusses the thromboxane A2 mechanism, as well as other possible biological

mechanisms demonstrating a relationship between testosterone and cardiovascular events. Pls.' Resp. to Defs.' SOMF, Ex. 3 (Gerstman Report) at 91–92. In discussing these mechanisms, Dr. Gerstman relies primarily on studies that existed prior to 2010, when the first bellwether plaintiff suffered a cardiovascular injury. He concludes that "several lines of biological evidence support the epidemiologic finding of an increased risk of heart attack and stroke with testosterone supplementation." *Id*. at 92.

Plaintiffs also provide the expert report of Dr. Hossein Ardehali. Dr. Ardehali opines that "[e]xogenously administered testosterone therapy in men increases the risk of a major cardiovascular event." Pls.' Resp. to Defs.' SOMF, Ex. 9 (Ardehali Report) at 7. Dr. Ardehali details the various mechanisms by which use of testosterone can increase the risk of cardiovascular injury, including through an effect on (1) thromboxane A2; (2) estradiol levels; (c) erythropoiesis; and (d) nitric oxide. *Id*. at 67. He also indicates that the scientific community began looking into the effect that testosterone has on cardiovascular risk as early as 1990. *Id*. at 66. Dr. Ardehali cites numerous studies and reports as evidence of the existence of a causal relationship, many of which were published prior to plaintiffs' injuries. *See id*. at 103–14.

Dr. Ardehali also reviewed numerous documents specific to AndroGel and determined that by 2007 there was reasonable evidence of a causal association between AndroGel therapy and cardiovascular injury. *See id*. at Appendix C. In drawing this conclusion, he relied primarily on AbbVie's signal evaluation reports, the PSURs AbbVie submitted to the FDA, and the FDA's own database on adverse event reports. *See id.*, Appendix C at 1. Dr. Ardehali concluded that the adverse event reports from individuals who had used AndroGel and experienced a cardiovascular

injury supported the existence of a causal association. A reasonable jury could infer from this evidence that AbbVie reasonably should have known that AndroGel increased cardiovascular risk.

AbbVie argues that Dr. Ardehali's "long-after-the-fact litigation work" does not give rise to a genuine dispute of fact, because he admitted that he does not have training in pharmacovigilance and did not use FDA guidelines when analyzing the adverse event reports. Defs.' Mot. for Summ. J. at 19–20. AbbVie points to no case law, however, indicating that whether a manufacturer reasonably should have known of a particular risk hinges on whether the FDA's guidelines have been met. The fact that the FDA considered the same evidence and concluded that no safety signal existed may support AbbVie's argument, but it does not prevent Dr. Ardehali's opinion from giving rise to a genuine dispute on this particular issue. Dr. Ardehali reviews both the scientific literature and the adverse event reports that would have been available to AbbVie prior to plaintiffs' injuries to conclude that an expert in this field—as AbbVie is deemed to be—reasonably should have known that use of TRT drugs is associated with an increased risk of cardiovascular injury.

Plaintiffs also offer the Basaria article, which was published before any of the four plaintiffs at issue suffered their cardiovascular injury, and concluded that use of testosterone gel is associated with an increased risk of adverse cardiovascular events. Basaria Article at 115. AbbVie argues that this study should be discounted due to the fact that the authors acknowledged that the results might be due to chance alone. Defs.' Mot. for Summ. J. at 88. AbbVie argues that plaintiffs cannot as a matter of law rely on an article "where the authors of a study themselves are unwilling to suggest a

causal link." *Id*. But although the authors did concede that the results may have been due to chance, they also stated in the conclusion of their study that "[i]n this population of older men with limitations in mobility and a high prevalence of chronic disease, the application of a testosterone gel was associated with an increased risk of cardiovascular adverse events." Basaria Article at 109. Even if this conclusion cannot be extrapolated to other populations, when considered in conjunction with the other evidence offered by plaintiffs it is sufficient to permit a reasonable jury to conclude that AbbVie reasonably should have known of a causal association.

Finally, the Court concludes that there is also ample evidence from which a reasonable jury could conclude that AbbVie had a duty to perform additional tests in order to better evaluate the effect of AndroGel on cardiovascular risk. One of the plaintiffs' experts, Dr. Peggy Pence, opines that the lack of safety data regarding the use of testosterone in elderly men was well-known as early as 2002. Pls.' Resp. to Defs.' SOMF, Ex. 4 (Pence Report) at 71. Dr. Pence discusses a number of articles published prior to 2010 that specifically address the need for further study to determine the effects of TRT drugs on cardiovascular risk. AbbVie itself recognized in 2005 that "[t]here is agreement in the literature that additional research is necessary." 2005 White Paper at 104. Further, in 2006 Canada's regulatory body, Health Canada, provided AbbVie with an assessment of regulatory issues surrounding testosterone therapy. *See* Pls.' Resp. to Defs.' SOMF, Ex. 11 (Health Canada Analysis). The analysis indicated that testosterone is known to increase hematocrit and that an above-normal hematocrit level "is associated with increased risk for vascular disease," including myocardial infarction, stroke, and thrombosis. *Id*. at 12. The analysis also stated that there is no

long-term clinical data available to determine the risk / benefit ratio of TRT in elderly men and that one is needed particularly to determine the incidence of "coronary events." *Id*. at 14. AbbVie asks the Court to discount this analysis because Health Canada was addressing "a different label, under a different regulatory regime, in a different country." Defs.' Reply at 8–9. But the analysis is not being used to dispute the adequacy of AbbVie's FDA-approved labels. Plaintiffs offer the analysis to show only that the scientific community agreed that more testing was required to determine whether drugs such as AndroGel increased the risk of cardiovascular injury.

In sum, a reasonable jury could infer that AbbVie reasonably should have known that there was a possible association between TRT drugs and increased cardiovascular risk and that it needed to perform additional safety testing. The Court therefore denies AbbVie's motion for summary judgment on claims brought by plaintiffs who experienced cardiovascular injuries to the extent they are based on whether AbbVie knew or should have known of an increased risk.

b. Information on VTE risk

Three bellwether plaintiffs allegedly suffered a VTE injury after taking AndroGel:

- Myers (pulmonary embolism on February 6, 2008)
- Nolte (pulmonary embolism on November 1, 2012)
- Rowley (DVT on April 27, 2013)

The Court considers the scientific literature and other medical information available to AbbVie prior to these dates. AbbVie divides its argument between the evidence available prior to 2009 (which encompasses Myers), the evidence available prior to 2014 (which encompasses Nolte and Rowley), and the evidence available after 2014 (which does not encompass any of the bellwether plaintiffs). Defs.' Mot. for Summ J. at

91–95. Because the Court concludes that a genuine dispute exists regarding whether AbbVie knew or reasonably should have known that a risk of VTE injury existed prior to Myers's injury in 2008, it is unnecessary to consider the remaining time periods.

Plaintiffs have provided evidence from which a reasonable jury could conclude that AbbVie should have known by February 2008 that TRT drugs could lead to an increased risk of a VTE injury. Plaintiffs offer the expert report of Dr. Henry Rinder, who opines that exogenous testosterone increases the risk of VTE injuries. Pls.' Resp. to Defs.' SOMF, Ex. 8 (Rinder Report) at 1. Dr. Rinder describes a number of biologically plausible mechanisms by which testosterone can increase the risk of VTE injury, one of which is an increase in hematocrit. *Id*. at 1–2, 10–13. AbbVie acknowledges that as early as February 2000, the medical literature supported a need to monitor hematocrit in patients taking TRT. Defs.' Mot. for Summ. J. at 91. Further, when discussing other mechanisms, Dr. Rinder cites literature that was available prior to 2008. Rinder Report at 11–13. Dr. Rinder's opinion is supported by that of Dr. Gerstman, who similarly discussed mechanisms that can lead to thromboembolic events, including through an increase in estradiol. In doing so, Dr. Gerstman relied on literature that was available prior to 2008.

Dr. Rinder also reviewed adverse event reports for AndroGel and opines in his report that by 2004, "there was evidence of heightened risk of VTE in patients exposed to AndroGel." *Id*. at 18, Appendix A. AbbVie appears to criticize Dr. Rinder for the same reasons as it challenges Dr. Ardehali—namely, that Dr. Rinder is not an expert in pharmacovigilance and did not apply the FDA's signal detection guidance in his analysis. Defs.' Mot. for Summ. J. at 42–43. But as discussed earlier, the fact that Dr.

Rinder did not apply the FDA's standards for signal detection does not mean that his opinion is irrelevant in determining whether AbbVie reasonably should have known of an association between TRT drugs and increased risk of VTE injury. Further, Dr. Pence incorporated Dr. Rinder's analysis in her own report in concluding that by 2004 reasonable evidence of a causal association existed. Pence Report at 81. Dr. Pence agreed that the adverse event reports between 1992 and 2004 constitute "particularly compelling evidence" that an association existed. *Id*. at 81–82.

In sum, a reasonable jury could conclude that AbbVie reasonably should have known from the scientific literature and AndroGel's adverse event reports about an association between TRT drugs and increased risk of VTE injury. The Court therefore denies AbbVie's motion for summary judgment on claims brought by plaintiffs who experienced VTE injuries to the extent they are based on whether AbbVie knew or should have known of an increased risk.

2. Adequacy of warnings

AbbVie next argues that the warnings on the AndroGel label that existed prior to each of the plaintiffs' injuries were adequate as a matter of law to warn of the risks of cardiovascular and VTE injury. "Although the adequacy of warnings concerning drugs is generally a question of fact, it can become a question of law where the warning is accurate, clear and unambiguous." *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003) (internal quotation marks omitted). Warnings are generally adequate when they contain "a full and complete disclosure of the potential adverse reactions to the drug." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994).

a. Cardiovascular risk

The Court finds that a genuine dispute exists regarding whether AbbVie adequately warned physicians of all known or reasonably knowable cardiovascular risks associated with AndroGel. In arguing that its labels were adequate, AbbVie points first to three statements added to the label between 2000 and 2007. The first indicates that "[e]dema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal or hepatic disease." Defs.' SUDMF, Ex. 27 (2000 AndroGel Label) at ABBVIE-FST00355128. A reasonable jury could conclude, however, that this warning is insufficient to inform consumers that regardless of preexisting conditions AndroGel may increase the risk of cardiovascular injury. Further, a genuine dispute exists regarding whether this statement adequately apprises consumers of all possible types of cardiovascular injuries.

The second statement indicates that "[g]eriatric patients treated with androgens may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma." *Id*. AbbVie argues that this statement is sufficient to inform physicians that men over the age of 65 are at greater risk of serious side effects. But this warning does not specifically identify either cardiovascular or VTE injury—it refers only to effects on users' prostates. The third statement, added in December 2007, indicates that "there is insufficient long-term safety data in geriatric patients to assess the potential risks of cardiovascular disease." Dec. 2007 AndroGel Label at ABBVIE-FST14649560. But a reasonable jury could conclude that this does not constitute a "full and complete disclosure" of the risks reasonably knowable to AbbVie at this time, given that it does not identify a relationship between AndroGel and cardiovascular injury.

AbbVie also points to three sets of clinical guidelines published between 2002 and 2010, each of which stated in some form that whether TRT is associated with increased cardiovascular risk is uncertain. *See* Defs.' Mot. for Summ. J. at 99–100. AbbVie fails to explain, however, how these guidelines are relevant in determining whether the warnings that AbbVie provided on the AndroGel label were adequate. AbbVie has not cited to any case law that requires the Court to look to warnings other than those given by AbbVie in determining whether AbbVie has upheld its duty to warn consumers of the knowable risks of its product. Further, these guidelines suffer from the same potential deficiencies as those identified with the AndroGel label itself, given that they indicate only that TRT's association with cardiovascular risk remains uncertain.

Finally, AbbVie argues that communications from the FDA in 2014 further informed doctors about a possible increase in cardiovascular risk. But each of the bellwether plaintiffs bringing claims based on cardiovascular risk suffered an injury prior to 2014. Therefore any warnings AbbVie provided after their injuries are irrelevant in determining whether these four plaintiffs received adequate warnings.

In light of the Court's conclusion that a reasonable jury could find that AbbVie had reason to know that AndroGel increased the risk of cardiovascular injury, a reasonable jury could also conclude that the warnings AbbVie gave indicating that the state of research was uncertain failed to notify consumers of an association between the two. AbbVie is therefore not entitled to summary judgment based on the adequacy of its warnings with regard to the plaintiffs who suffered cardiovascular injuries.

b. VTE risk

AbbVie next argues that it provided adequate warnings regarding the risk of VTE

injury associated with AndroGel. AbbVie points to the fact that from the initial approval of AndroGel, the product's label instructed doctors to monitor hematocrit in order to detect polycythemia. Further, in 2007 AbbVie added a statement that specifically indicated that an increase in hematocrit could increase the risk of a thromboembolic event. But plaintiffs argue—and a reasonable jury could conclude—that these warnings did not adequately address the risk of VTE caused by a different mechanism and otherwise independent of an increase in hematocrit. This is relevant because it appears that both Myers and Rowley had normal levels of hematocrit at the time of their injuries. Therefore a genuine dispute exists regarding whether these statements provided physicians with adequate warning that AndroGel could lead to thrombotic events that would not be indicated by an increase in hematocrit.

c. Rebuttable presumption and overpromotion

AbbVie also argues that two of the states at issue here—Tennessee and Utah—employ a rebuttable presumption that FDA-approved warnings are adequate and therefore that the discussion above is irrelevant for plaintiffs Konrad and Rowley. Both Utah and Tennessee appear to apply a presumption of non-defectiveness for products manufactured in conformity with government standards. *See* Utah Code Ann. § 78B-6-703 (West); Tenn. Code Ann. § 29-28-104 (West). But plaintiffs can rebut this presumption by demonstrating that the product at issue was in fact unreasonably dangerous. *See Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 536 (Tenn. 2008); *Niemala v. Imperial Mfg., Inc.*, 2011 UT App. 333, ¶ 10, 263 P.3d 1191, 1196 (2011). And plaintiffs have presented evidence that AndroGel did not have any benefits for individuals who had "Low T" as opposed to classical hypogonadism. A reasonable jury

could conclude that AndroGel's risks outweighed its benefits and therefore that it was unreasonably dangerous.

And even if the warnings the Court has discussed adequately addressed the risk of cardiovascular and VTE injury, there is still reason to deny AbbVie's motion for summary judgment. Many states apply the overpromotion theory, under which a manufacturer can be liable for failure to warn even when the warnings were adequate if it engaged in an advertising campaign that in effect negated the warnings. *See Okuda v. Wyeth*, No. 1:04-CV-80 DN, 2012 WL 12337860, at *1 (D. Utah July 24, 2012) (considering motions *in limine*) (indicating that the overpromotion theory comes into play "if the warnings given were adequate and the prescribing physicians disregarded the warnings in reliance on the promotional materials"); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975) (applying North Carolina law) (indicating that a jury could infer that certain promotional materials provided to the physician were "a form of overpromotion which nullified the effect of even a valid warning on the package"); *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65, 507 P.2d 653, 661 (1975) ("[A]n adequate warning to the profession may be . . . nullified by overpromotion of the drug . . . which may have the effect of persuading the prescribing doctor to disregard the warnings given.").

Plaintiffs contend that AbbVie engaged in an overpromotion campaign when it exaggerated the benefits of AndroGel and promoted it "as a cure-all for numerous afflictions for which it was never tested or approved." Pls.' Resp. at 44. They argue essentially that this overpromotion skewed the prescribing physicians' risk / benefit assessments and caused them to disregard the AndroGel warnings. *Id*. at 46–47. And

the Court has elsewhere determined, in its ruling on another of the three motions for summary judgment brought by AbbVie, that a genuine dispute exists regarding whether AbbVie engaged in such a campaign and whether the physicians for each of these plaintiffs was impacted by it. Thus even for those plaintiffs for whom the warning otherwise might have been adequate—such as plaintiffs from states with a rebuttable presumption of adequacy or Nolte, who suffered a VTE injury with an accompanying increase in hematocrit—a genuine dispute exists regarding whether AbbVie's conduct amounted to overpromotion and caused the prescribing physicians to disregard the otherwise adequate warnings. The Court therefore denies AbbVie's motion for summary judgment on plaintiffs' failure to warn claims on the basis that the warnings given were adequate.

3. Proximate cause

The standard for proximate cause on a failure to warn claim varies somewhat among different states. Generally speaking, a plaintiff must show that had the manufacturer provided the warning at issue, the plaintiff's injury would have been avoided. Some jurisdictions apply the heeding presumption, which indicates "that where a warning is inadequate, the plaintiff is entitled to a rebuttable presumption that an adequate warning would have been heeded if one had been given." *Thom*, 353 F.3d at 855. AbbVie argues that four plaintiffs—Cribbs, Konrad, Myers, and Rowley—have not provided evidence giving rise to a genuine dispute on this point because each of their physicians testified that they still would have prescribed AndroGel even if the desired warnings had been included. Defs.' Mot. for Summ. J. at 106.

a. Cribbs

Under North Carolina law, a plaintiff in a failure to warn case must demonstrate that the desired warning would have altered the physician's care and avoided the plaintiff's injury. *See Holley v. Burroughs Wellcome Co.*, 318 N.C. 352, 356, 348 S.E.2d 772, 774–75 (1986). AbbVie argues that Cribbs cannot meet this element because his prescribing physician, Dr. Mark Ottelin, testified that he continued to prescribe AndroGel for Cribbs even after receiving an alert from the FDA that it was investigating the risk of stroke and heart attack in men taking testosterone products. Pls.' Resp. to Defs.' SOMF, Ex. 16 (Ottelin Dep.) at 130:18–132:2. But Dr. Ottelin also testified that his process in prescribing AndroGel to Cribbs would have been to discuss the drug and all its potential complications and then permit Cribbs to choose whether to proceed. *Id*. at 87:8–16. Dr. Ottelin testified that he would not have discussed cardiovascular complications with Cribbs when he initially prescribed AndroGel because that information did not exist at that time. *Id*. at 87:24–88:2. And Cribbs testified that he decided to stop taking AndroGel after he saw a commercial indicating that taking AndroGel could lead to heart attacks. Pls.' Resp. to Defs.' SOMF, Ex. 17 (Cribbs Dep.) at 156:2–8. A reasonable jury could infer from this evidence that, had AbbVie provided Dr. Ottelin with the warning regarding cardiovascular risk, he would have informed Cribbs of this risk, and Cribbs would have decided not to take AndroGel. AbbVie is not entitled to summary judgment on Cribbs's failure to warn claims on the basis of lack of proximate cause.

b. Konrad

To show proximate cause under Tennessee law, the plaintiff must show "that a

warning would have altered the doctor's actions and that the change in the doctor's actions would have averted the patient's injury." *Payne*, 767 F.3d at 531. Because Tennessee law has not adopted the heeding presumption, *id*. at 532–33, Konrad must present evidence from which a reasonable jury could conclude that his injury would have been avoided if his doctor had received a different warning.

AbbVie argues that Konrad cannot do so because his doctor, Steven Overby, testified that the primary effect of the new warnings was to reduce the number of patients that requested testosterone replacement medication. Defs.' SUDMF, Ex. 111 (Overby Dep.) at 130:23–131:17. Dr. Overby further stated that "it is not necessarily that [he is] fearful of using the prescription" and that Konrad had a clear screening workup before he prescribed AndroGel. *Id*. at 131:18–24. Therefore, AbbVie argues, Dr. Overby has not been discouraged from prescribing AndroGel and still would have done so for Konrad, regardless of additional warnings.

But Dr. Overby also testified that his "prescription writing habits are basically run by the patient request or the patient volume that demands a certain type of prescription." *Id*. at 132:1–4. Further, he testified that, had the information in the 2015 label regarding the risk of heart attacks and stroke been available in 2010, he would have discussed these risks with Konrad before writing a prescription. *Id*. at 133:14–22. Dr. Overby stated he would also have included the later-added information regarding DVT into his risk-benefit analysis when determining whether to prescribe AndroGel. *Id*. at 133:23–134:4. And Konrad testified that it would have been important to him "to know of any potential increased risk of heart attacks or strokes associated with AndroGel use prior to making [his] decision to take the drug." Pls.' Resp. to Defs.'

SOMF, Ex. 19 (Konrad Dep.) at 226:6–9. The court in *Payne* indicated that causation "ultimately rests with the patient's decision to take or reject the medication." *Payne*, 767 F.3d at 532. A reasonable jury could infer from the evidence cited by plaintiffs that Dr. Overby would have informed Konrad about the associated cardiovascular risks and that Konrad would have chosen not to take AndroGel. *See Smith v. Pfizer Inc.*, 688 F. Supp. 2d 735, 746 (M.D. Tenn. 2010) (denying summary judgment on the issue of causation where plaintiff's physician would have warned him about the side effects at issue and evidence showed that plaintiff was concerned with these particular side effects). AbbVie is not entitled to summary judgment on Konrad's failure to warn claims on the basis of lack of proximate cause.

c. Myers

Under Arizona law, Myers must show that if AbbVie had issued a proper warning, he would not have taken AndroGel. *See D'Agnese v. Novartis Pharm. Corp.*, 952 F. Supp. 2d 880, 890 (D. Ariz. 2013). Arizona courts apply the heeding presumption to their determination of proximate cause. *Id*. AbbVie argues that there is no genuine dispute regarding proximate cause because Dr. Michaela Tong, Myers's prescribing physician, testified that she warned him of the risk of thromboembolic events and that additional VTE warnings would not have affected her decision whether to prescribe AndroGel. Defs.' SUDMF, Ex. 109 (Tong Dep.) at 109:2–16, 114:16–21. But Myers testified during his deposition that he does not recall Dr. Tong providing any warning about risks associated with AndroGel and that he would remember if this occurred. Pls.' Resp. to Defs.' SOMF, Ex. 19 (Myers's Dep.) at 153:21–154:9. Myers also testified that he would have trusted Dr. Tong to warn him of any adverse effects associated with

AndroGel. *Id*. at 156:3–10. Further, although Dr. Tong testified that she provided Myers with the warning on possible VTE events that existed in the label in 2007, this label only addressed VTE events associated with an increase in hematocrit. Dr. Tong did not warn Myers of the risk of VTE injuries that could occur independently of an increase in hematocrit. *See* Tong Dep. at 158:15–162:20. A reasonable jury could infer from this evidence that Myers was not fully apprised of the risks associated with AndroGel and that he would not have taken the drug if he had been fully informed. Because AbbVie does not offer any evidence that Myers would still have taken the drug even with these warnings, it is not entitled to summary judgment on Myers's failure to warn claims on the basis of lack of proximate cause.

d. Rowley

In a failure to warn claim brought under the law of Utah, a plaintiff "must show . . . that had warnings been provided, the injured party would have altered his use of the product or taken added precautions to avoid the injury." *House*, 929 P.2d at 346. Courts in Utah apply the heeding presumption. *See id.* Proximate causation is generally a question for the jury—"[o]nly in rare cases may a trial judge rule as a matter of law on the issue of proximate cause." *Steffensen v. Smith's Mgmt. Corp.*, 820 P.2d 482, 486 (Utah Ct. App. 1991).

AbbVie argues that Rowley has failed to present evidence to support proximate cause because his prescribing medical professional, physician's assistant Teryl Hunsaker, testified during his deposition that he was aware of the risk of blood clots and that he took this risk into account when making his initial prescribing decision. Pls.' Resp. to Defs.' SOMF, Ex. 23 (Hunsaker Dep.) at 64:12–23, 115:1–10. But Hunsaker

also testified that he was unaware of the risk of DVT at the time that he first prescribed AndroGel to Rowley. *Id*. at 114:17–21. More importantly, when asked whether he would have prescribed AndroGel to Rowley had he been advised that AndroGel led to an increased risk of VTE independent of polycythemia, Hunsaker testified that he did not know and that he would have discussed this risk with Rowley before prescribing the medication. *Id*. at 112:15–113:3. This testimony is sufficient to give rise to a genuine dispute regarding whether AbbVie's failure to provide this warning was the proximate cause of Rowley's injury. AbbVie is not entitled to summary judgment on Rowley's failure to warn claims on the basis of lack of proximate cause.

4. Statute of limitations

AbbVie also contends that Myers's failure to warn claims are barred by the statute of limitations. It argues that Myers's cause of action accrued in February 2008 when he suffered a pulmonary embolism. Because more than two years have elapsed since this event, AbbVie contends, Myers is barred from bringing his claim.

The Arizona Supreme Court has indicated that the statute of limitations is not automatically triggered each time a professional's services may have brought about an adverse result. *Walk v. Ring*, 202 Ariz. 310, 314–15, 44 P.3d 990, 994–95 (2002) (en banc) (considering a claim for medical malpractice). Instead, the statute begins to run only when the plaintiff knows, or reasonably should know, of the wrong committed by the defendant. *Id*. at 315, 44 P.3d at 995. The court stated that "it is not enough that a plaintiff comprehends a 'what'; there must also be reason to connect the 'what' to a particular 'who' in such a way that a reasonable person would be on notice to investigate whether the injury might result from fault." *Id*. at 316, 44 P.3d at 996. Here,

Myers's "what" certainly occurred in February 2008 when he suffered a pulmonary embolism. And AbbVie argues that Myers reasonably could have discovered the existence of his claims against AbbVie in 2008 because the AndroGel label that existed at the time included the statement that an increase in red blood cell mass may increase the risk for a thromboembolic event. Defs.' Mot. for Summ. J. at 91–93. But the statement on the label highlighted the risk of thromboembolic event only as related to an increase in red blood cells. And Myers had a normal hematocrit (the ratio of red blood cells to total volume of blood) at the time of his pulmonary embolism. The Court finds that a reasonable jury could conclude that Myer did not have a reason to connect this injury with AndroGel until much later—specifically, the point in time when he had reason to believe that AndroGel could lead to VTE injury independent of an increase in hematocrit. Because there is a genuine dispute regarding when Myers reasonably should have discovered his claims against AbbVie, AbbVie is not entitled to summary judgment on Myers's claims based on the statute of limitations.

D. Other state law claims

1. Strict liability—design defect

Plaintiffs Frost, Konrad, Mitchell, Nolte, and Rowley allege that AbbVie is strictly liable for manufacturing AndroGel with a defective design. Plaintiffs concede that Utah law precludes Rowley from bringing this claim. Pls.' Resp. at 64 n.28. The Court therefore grants summary judgment in favor of AbbVie on Rowley's strict liability design defect claim. AbbVie argues that three of the remaining plaintiffs live in states which provide manufacturers with immunity from strict liability design defect claims when the drug at issue has been approved by the FDA. Defs.' Mot. for Summ. J. at 108–109.

With regard to Nolte, AbbVie argues that he cannot meet the elements of a strict liability design defect claim under Arizona law. *Id*. at 109–10.

AbbVie is correct that three of the states at issue here—California (Frost), Tennessee (Konrad), and Oregon (Mitchell)—appear to have adopted comment (k) to section 402A of the Restatement (Second) of Torts, which states that manufacturers of products that are "unavoidably unsafe," such as prescription medications, are "not to be held to strict liability for unfortunate consequences attending their use." *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1149 (D. Or. 1989); *see also Brown v. Superior Court*, 44 Cal. 3d 1049, 1066–67, 751 P.2d 470, 481 (1988); Or. Rev. Stat. Ann. § 30.920(3); *Rodriguez v. Stryker Corp.*, No. 2:08–0124, 2011 WL 31462, at *6 (M.D. Tenn. Jan. 5, 2011). But comment (k) confers this immunity only "with the qualification that [the drugs] are properly prepared and marketed, *and proper warning is given*." *Allen*, 708 F. Supp. at 1149 (emphasis added) (citing Restatement (2d) of Torts § 402A, cmt. k (1965)). Therefore numerous courts have held that a drug manufacturer receives immunity from strict liability design defect claims only when there is no dispute regarding whether the manufacturer provided adequate warnings. *See Allen*, 708 F. Supp. at 1149; *J.F. ex rel. Moore v. McKesson Corp.*, No. 1:13-CV-01699-LJO-JLT, 2014 WL 202737, at *7-8 (E.D. Cal. Jan. 17, 2014); *Harwell v. Am. Med. Sys., Inc.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992). AbbVie is therefore not entitled to summary judgment on the basis of comment (k), because a genuine dispute exists regarding whether it provided adequate warnings.

AbbVie also argues that Nolte has failed to provide evidence to support the elements of a strict liability design defect claim under Arizona law. AbbVie contends

that Arizona courts apply the standard from the Restatement (Third) of Torts, under which a prescription drug is not considered to be defectively designed unless "a reasonable healthcare provider would not prescribe the drug for any class of patients." Defs.' Mot. for Summ. J. at 109 (internal quotation marks omitted). In support, AbbVie points to two federal district court cases from Arizona that cite this standard when considering design defect claims brought under Arizona law. *See Harrison v. Howmedica Osteonics Corp.*, No. CIV 06-0745 PHX RCB, 2008 WL 906585, at *21 (D. Ariz. Mar. 31, 2008); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999). But the court in *Gebhardt* itself acknowledged that "no Arizona case has formally adopted the Restatement (Third) of Torts." *Gebhardt*, 191 F.R.D. at 185. And Arizona courts considering strict liability design defect claims use the "risk / benefit analysis" to determine whether it was reasonable for the manufacturer to put his product on the market. *Golonka v. Gen. Motors Corp.*, 204 Ariz. 575, 581–82, 65 P.3d 956, 962–63 (Ariz. App. Ct. 2003). This test considers whether the manufacturer would continue to market the product in light of the product's potentially dangerous consequences. *Gomulka v. Yavapai Mach. and Auto Parts, Inc.*, 155 Ariz. 239, 243, 745 P.2d 986, 990 (Ariz. App. Ct. 1987). Thus Nolte's claim hinges on whether he can demonstrate that a reasonable manufacturer in AbbVie's position would have continued to market AndroGel in light of the attendant cardiovascular and VTE risks. Nolte argues that a reasonable manufacturer would not have done so because the benefits that AbbVie claimed for treating men with "Low T" did not actually exist and therefore could not have outweighed the risks. The Court finds that this is sufficient to give rise to a genuine dispute regarding whether Nolte can establish the elements of strict liability for a design

defect under Arizona law. Without a clear statement from the Arizona courts on whether the state has adopted this "any class of patients" standard, the Court declines to modify the risk / benefit analysis that Arizona courts have applied for years.

The Court therefore grants AbbVie's motion for summary judgment on the strict liability design defect claim brought by Rowley but otherwise denies the motion for summary judgment on these claims.

2. Negligence—design defect

AbbVie also argues that the Court should grant it summary judgment on plaintiffs' negligence claims to the extent that they are based on defective design. Defs.' Mot. for Summ. J. at 110. AbbVie contends that any such claims are preempted by federal law, relying primarily on *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015). Design defect claims typically require the plaintiff to demonstrate that that there was a reasonably feasible alternative design. *See, e.g.*, *DeWitt v. Eveready Battery Co., Inc.*, 144 N.C. App. 143, 154–55, 550 S.E.2d 511, 518–19 (2001). In *Yates*, the court concluded that any negligence claim based on the argument that a manufacturer should have used employed an alternative design for its drug after it was approved by the FDA was preempted by federal law because FDA regulations prohibit a manufacturer from making major changes to the formulation of the drug provided in the approved application. *Yates*, 808 F.3d at 298. The court then indicated that any argument based on an alternative pre-approval design was too attenuated because it would require the court to speculate on whether the FDA would have approved the alternative design and whether the plaintiffs would still have selected the drug in its alternate form. *Id*. at 299.

Plaintiffs argue that none of this analysis applies to their claims for negligent design defect because they "do not allege a safer alternative formulation or brand of testosterone would have avoided their injuries." Pls.' Resp. at 65. Instead, plaintiffs argue, they are asserting that there is no formulation of testosterone that would be effective to treat individuals with age-related hypogonadism, which they refer to as an "illusory" condition that does not require TRT. *Id*. But plaintiffs cite no case law which supports their contention that they can bring a negligent design defect claim without demonstrating the existence of a feasible alternative design. Plaintiffs' characterization of these claims demonstrates that they are actually just a repackaging of their off-label marketing claims—that AbbVie never should have promoted AndroGel for use by individuals with age-related hypogonadism or "Low T." The Court grants summary judgment in favor of AbbVie on these claims.

3. Implied warranty

AbbVie argues in a footnote that manufacturers of prescription drugs receive the same comment (k) immunity from liability on implied warranty claims as they receive on strict liability design defect claims. Defs.' Mot. for Summ. J. at 109 n.57. This is true under Utah law, which means that the Court must also grant summary judgment to AbbVie on Rowley's claim for breach of implied warranty. *See Straub v. Fisher & Paykel Health Care*, 990 P.2d 384, 389 n.1 (Utah 1999). As for the remaining plaintiffs, even if AbbVie is correct, the Court determined that a genuine dispute exists regarding whether AbbVie is entitled to comment (k) immunity due to its alleged failure to provide adequate warnings. The Court therefore denies AbbVie's motion for summary judgment on the remaining plaintiffs' implied warranty claims for the same reason.

4. Unjust enrichment

AbbVie also argues that it is entitled to summary judgment on Cribbs's claim of unjust enrichment. AbbVie first argues that Cribbs cannot show that he conferred a benefit directly on AbbVie as required under North Carolina law. Defs.' Mot. for Summ. J. at 112. But both appellate courts in North Carolina and federal courts applying North Carolina law have held that a plaintiff can bring a claim for unjust enrichment even if he has not directly conferred a benefit on the defendant. *See New Prime, Inc. v. Harris Transp. Co.*, No. COA12-271, 2012 WL 3192718, at *2–3 (N.C. App. Ct. Aug. 7, 2012); *Metric Constructors, Inc. v. Bank of Tokyo-Mitsubishi, Ltd.*, 72 F. App'x 916, 920–21 (4th Cir. 2003); *In re Processed Egg Products Antitrust Litig.*, 851 F. Supp. 2d 867, 932 (E.D. Penn. 2012). AbbVie next argues that Cribbs cannot show that he did not receive the benefit that he paid for, because he has admitted that he saw an overall improvement in his well-being after taking AndroGel. Defs.' Mot. for Summ. J. at 112. But Cribbs also alleges that he suffered a myocardial infarction due to taking AndroGel and thus that he did not receive the safe treatment for which he paid. This is sufficient to give rise to a genuine dispute regarding whether AbbVie was unjustly enriched. The Court therefore denies AbbVie's motion for summary judgment on Cribbs's claim of unjust enrichment.

D. Punitive damages

Finally, AbbVie argues that plaintiffs' requests for punitive damages fail as a matter of law, either because the states in which the plaintiffs reside bar punitive damages in these types of cases or because the plaintiffs have failed to provide clear and convincing evidence that AbbVie acted fraudulently or maliciously. Defs.' Mot for Summ. J. at 111–12. Plaintiffs argue that the law of Illinois—AbbVie's home state—

governs the question of punitive damages and that a genuine dispute exists regarding whether plaintiffs can meet the standard under Illinois law.

1. Choice of law

Plaintiffs contend that this Court should apply Illinois choice of law rules when determining which state's law governs the availability and award of punitive damages. Pls.' Resp. at 66–69. AbbVie does not argue otherwise, though it contends that under Illinois choice of law rules, the punitive damages determination is governed by the law of plaintiffs' home states. *See* Reply Mem. in Further Supp. of Defs.' Mot. for Summ. J. on Pls.' Failure-To-Warn Claims (Defs.' Reply) at 14 & n.16.

The Seventh Circuit has indicated that in "foreign cases filed directly in a district court as a part of ongoing multidistrict litigation," courts generally should treat the cases, for purposes of applicable choice of law rules, as originating outside the district and thus should apply the choice of law rules of the originating states. *Dobbs v. DePuy Orthopedics, Inc.*, 842 F.3d 1045, 1049 (7th Cir. 2016). But this rule applies only to *foreign* cases that were directly filed in the district overseeing the MDL. As established by the Court in Case Management Order No. 12, any actions filed in this MDL proceeding after October 24, 2014 solely against AbbVie are treated as originally filed in this district, if the plaintiff pleads in his complaint that venue is proper in this district. *See* dkt. no. 440 (Case Mgmt. Order No. 12 Regarding the Filing of Actions in the Northern District of Ill. or Directly in the MDL Proceedings) at II.B.ii. The bellwether plaintiffs have brought their claims solely against AbbVie and have each alleged that venue is proper in the Northern District of Illinois. Thus these cases in fact originate in this district.

Further, the Seventh Circuit has also indicated that "[w]here the parties agree on the law that governs a dispute, and there is at least a reasonable relation between the dispute and the forum whose law has been selected by the parties, [courts] forego an independent analysis of the choice-of-law issue and apply the parties' choice." *Harter v. Iowa Grain Co.*, 220 F.3d 544, 559 n.13 (7th Cir. 2000) (internal quotation marks omitted). Neither party argues that the choice of law rules of a state other than Illinois should apply to the selection of the law on punitive damages. And there is a reasonable relation between the dispute and Illinois, because this Court sits in Illinois and AbbVie is located in Illinois. The Court therefore applies Illinois choice of law rules when determining what law governs plaintiffs' requests for punitive damages.

Illinois courts employ the "most significant contacts" test to resolve conflicts of law. *Miller v. Long-Airdox Co.*, 914 F.2d 976, 978 (7th Cir. 1990). Illinois law applies a strong presumption that the law of the state where the injury occurred governs in a personal injury case, which can be overcome only "by showing a more or greater significant relationship to another state." *Townsend v. Sears, Roebuck & Co.*, 227 Ill. 2d 147, 163–64, 879 N.E.2d 893, 903 (2007). A court considers where the injury occurred, where the conduct that caused the injury occurred, the domiciles of the parties, and where the parties' relationship is centered. *Id*. at 160, 879 N.E.2d at 901. The Court also takes into consideration the relevant policies of the forum, the relevant policies of the interested states, and the relative interests of those states in the determination of the particular issue. *Id*. at 170, 879 N.E.2d at 906–07.

Here, the most significant contacts occurred both in plaintiffs' home states (where the injuries occurred) and in AbbVie's home state (where the conduct that allegedly

caused the injury took place) and therefore do not favor one party over the other. In considering the purpose of punitive damages, however, the Court concludes that Illinois has the greatest interest in governing the determination of punitive damages. Punitive damages serve a public goal of punishing the defendant for its wrongdoing and protecting the public from future misconduct, either by the defendant or by others. *Ziarko v. Soo Line R. Co.*, 161 Ill. 2d 267, 276, 641 N.E.2d 402, 407 (1994). In the Court's view, the state in which a defendant is domiciled therefore tends to have a stronger policy interest in whether punitive damages are available than the state in which the plaintiff's injury occurred. Thus Illinois' interest in regulating AbbVie's conduct outweighs whatever interest plaintiffs' home states have in protecting non-resident businesses against excessive liability.

AbbVie cites to *Hammond v. System Transport, Inc.*, No. 11 CV 1295, 2012 WL 3234865 (C.D. Ill. Aug. 6, 2012), in which the court analyzed the same choice-of-law authority—and this Court's decision in a prior case—and decided to apply the law of the plaintiff's home state regarding the imposition of punitive damages. The Court respectfully disagrees with the analysis in that case and found no Illinois case law that suggests a different conclusion. The Court therefore applies Illinois law to the plaintiffs' requests for punitive damages.

2. Punitive damages standard

Under Illinois law, punitive damages are awarded "only where the defendant's conduct is willful or outrageous due to evil motive or a reckless indifference to the rights of others." *Franz v. Calaco Dev. Corp.*, 352 Ill. App. 3d 1129, 1137, 818 N.E.2d 357, 366 (2004). The Court finds that a genuine dispute exists regarding whether AbbVie's

conduct was sufficiently willful or outrageous. Plaintiffs have provided evidence from which a reasonable jury could conclude that AbbVie knew that AndroGel increased the risk of cardiovascular and VTE injury and yet failed to provide adequate warnings. Further, as the Court has concluded in a separate ruling, a reasonable jury could infer that AbbVie promoted AndroGel for the treatment of a condition referred to as "Low T," knowing that AndroGel had no cognizable benefits for this class of patients. Taken together, plaintiffs have provided sufficient evidence to give rise to a genuine dispute regarding whether AbbVie advertised AndroGel to a class of patients who did not need the drug, without warning of severe side effects. A reasonable jury could find this conduct sufficiently willful or outrageous to support a claim for punitive damages. *See Proctor v. Davis*, 291 Ill. App. 3d 265, 285–286, 682 N.E.2d 1203, 1216 (1997) (finding sufficient evidence for a punitive damages award where defendant "not only knew of the adverse effects of periocular use of [the product], but promoted and developed this off-label use). The Court therefore denies AbbVie's motion for summary judgment on plaintiffs' requests for punitive damages.

Conclusion

For the foregoing reasons, the Court grants AbbVie's motion for summary judgment [dkt. no. 1745] on Rowley's strict liability design defect claim, Rowley's breach of implied warranty claim, and all of the AbbVie bellwether plaintiffs' negligent design defect claims but otherwise denies the motion.

MATTHEW F. KENNELLY
United States District Judge

Date: May 8, 2017